510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:
k061328

B. Purpose for Submission:
Addition of software allowing data transfer to 3rd party servers

C. Manufacturer and Instrument Name:
e-San Limited, Think Positive (t+) Diabetes Management System (e-San Bluetooth Cradle)

D. Type of Test or Tests Performed:
This device does not directly test glucose. This is an accessory to a previously cleared meter (LifeScan OneTouch® Ultra® Blood Glucose Monitoring System k002134).

E. System Descriptions:

1. Device Description:
   The device is the e-San Bluetooth Cradle and it is connected to a LifeScan OneTouch® Ultra® Blood Glucose Monitoring System and uses short-range low power wireless transmission (Bluetooth V1.2) to send the data to a Bluetooth compatible cellular telephone such as the Nokia Model 6230 and provides a patient diary software application. The t+ Diabetes System enables users to store and display data on the cellular phone, and to send data from the cellular telephone to a remote database for storage and display via the internet.

   The Cradle is battery powered and fits over and plugs into a 3.5 mm 3-wire stereo socket that is in the end of the OneTouch® Ultra® device.

   The Cradle is to be sold over-the-counter (OTC), as it plugs onto OneTouch® Ultra® glucose meter which is also an OTC device.

2. Principles of Operation:
   Glucose Monitoring System - Subject of k002134.

   The e-San Bluetooth Cradle provides transparent serial cable replacement between LifeScan OneTouch® Ultra® Blood Glucose Monitoring System and a Bluetooth enabled cellular phone, e.g. Nokia 6600, which allows patient's measurement data to be downloaded to a cellular telephone.

   It is interfaced to the serial for the LifeScan OneTouch® Ultra® Blood Glucose Monitoring System via 3.5mm stereo plug.

It is battery operated with a 6 month life span at 6 uses per day. Power-saving mechanisms are employed in order to maximize batter life, e.g. auto-off, remote-shutdown, RF TX power control, etc.

The product is designed to match the ergonomics, size and weight of the OneTouch® Ultra® Blood Glucose Monitoring System while maintain sound mechanical support for the serial interface connector.

In order to minimize the size of the device, it utilizes an internal Bluetooth antenna.

3. Modes of Operation:
   Wireless data transfer of stored glucose measurements.
4. Specimen Identification:
   Subject of k002134.
5. Specimen Sampling and Handling:
   Subject of k002134.
6. Calibration:
   Subject of k002134.
7. Quality Control:
   Subject of k002134.
8. Software:
   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:
   Yes___X___ or No_____

F. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1345, Glucose Test System
2. Classification:
   Class II
3. Product code:
   NBW
4. Panel:
   75 (Clinical Chemistry)

G. Intended Use:

1. Indication(s) for Use:
   The e-San Bluetooth Cradle is intended to be used by patients at home. It is physically connected to a LifeScan OneTouch® Ultra® Blood Glucose Monitoring System and wirelessly sends the signals (via Bluetooth V1.2) to a Bluetooth enabled cellular phone such as the Nokia 6230.

   The e-San Bluetooth Cradle serves as the remote communication link between the LifeScan OneTouch® Ultra® Blood Glucose Monitoring System and a cellular telephone.

The t+ Diabetes System enables users to store and display data on the cellular phone, and to send data from the cellular telephone to a remote database for storage and display via the internet.

2. Special Conditions for Use Statement(s):
None.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:
k052343

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Cradle	Cradle sends data to cellular phone	Cradle sends data to cellular phone

Differences		
Item	Device	Predicate
Cradle	Cradle sends data to cellular phone which can then send to a 3rd party server for data storage and display.	Predicate does not have this capability.

I. Special Control/Guidance Document Referenced (if applicable):
None referenced.

J. Performance Characteristics*:*

1. Analytical Performance:
   a. *Accuracy*:
   Subject of k002134.
   b. *Precision/Reproducibility*:
   Subject of k002134.
   c. *Linearity*:
   Subject of k002134.
   d. *Carryover*:
   Subject of k002134.
   e. *Interfering Substances*:
   Subject of k002134.

2. Other Supportive Instrument Performance Data Not Covered Above:

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.